

### Remarks/Arguments

Claims 1 to 7 are pending. Claim 1 has been amended. Claim 1 has been amended to recite more structure of the bottle and the content (copy attached) of page 4, line 22, to page 5, first line.

The Office Action stated: that the listing of references in the specification is not a proper information disclosure statement; that 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, 'the list may not be incorporated into the specification but must be submitted in a separate paper.'; and that, therefore, unless the references have been cited by the Examiner on form PTO-892, they have not been considered. The Examiner assertion is not in point. Applicants were dealing with what the Examiner had to consider in resolving the level of ordinary skill in the art. In such case, all references, information, etc., of record in the application must be considered by the Examiner. Until the Examiner resolves the level of ordinary skill in the art (and sets out his analysis and the supporting facts, reasons, etc.), any obviousness rejection (as here) is defective. This is required by Patent Office policy and the Supreme Court's Graham and KSR decisions.

The Office Action stated: that in response to the Examiner's notification in paragraph 1 that the listing of references in the specification is not a proper information disclosure statement; that applicants argue that the Examiner is required to read and consider all of the disclosure in the application, including the

prior art disclosed and discussed in the application; that the disclosure has been considered including applicants' description of the background art; that, however, considering applicants' description of a reference is not equivalent to considering the reference itself; and that, consequently, references which were not indicated as being considered in the Notice of References Cited or the Information Disclosure Statement have not been considered. In making an obviousness rejection the Examiner has the duty to make a prior art search – when, as here, he has reason to believe that the reference is pertinent to his resolution of the level of ordinary skill in the art, he has a duty to seek out such reference.

Applicants are filing an IDS with a copy of the involved reference in a couple of days.

The Office Action stated that the following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action;

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in Section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 5 and 7 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0153386 to

Uetake et al. (Uetake) in view of U.S. Patent No. 6,030,632 to Sawan et al. (Sawan). Applicants traverse this rejection. Note that the Examiner has not asserted that applicants' claimed invention is obvious to one ordinarily skilled in the art in view of the combination of the two rejection references.

The combination of Uetake and Sawan does not result in applicants' claimed invention, hence applicants' claimed invention is not unpatentable under Section 103(a).

Amended independent Claim 1 recites:

"wherein the internal layer bag has memory which expands said internal layer bag and generates negative pressure in the internal layer bag so that a pressure difference between the negative pressure and the ambient pressure becomes higher than the filtration resistance, and the negative pressure aspirates liquid that remains in downstream side of the filtration film to upstream side of the filtration film".

Applicants believe that the above is not obvious from the rejection combination of Uetake and Sawan.

Applicants believe that the container disclosed in Uetake cannot aspirate liquid that remains in the downstream side of the film by reason of having a valve 11.

Sawan discloses that the prefilter 15 is spaced upstream from filter 6 (col. 11, lines 28 and 29). More specifically, the prefilter 15 is not placed on the upstream side of the filtration film.

As a result, the rejection combination of Uetake and Sawan does not result in amended independent Claim 1, and hence none of applicants' claims are obvious over the rejection references (singularly and in combination).

Furthermore, the feature that the pressure difference between the negative pressure and the ambient pressure becomes higher than the filtration resistance is not indicated in Uetake, Sawan or Shiraishi. All of the obviousness rejections containing Shiraishi also fail.

The Examiner is requested to allow all of the claims over the applied prior art.

The Office Action stated that, in reference to Claim 1, Uetake teaches:

A container with a filter (1) comprising:  
a bottle (2) having a mouth portion (2a);  
a plug body (3) placed on the mouth portion and providing a discharging pass (10) for discharging internal liquid kept in the bottle;  
a filter (7,50) provided in the discharging pass;  
said filter (7,50) has a filtration film (7) to filter out bacteria for preventing bacteria from percolating from downstream side to upstream side in the direction of discharging ([0034]).

Applicants disagree with this statement. Sawan does not cure the defects of Uetake in the search for applicants' claimed invention.

The Office Action stated that Uetake does not teach the following which is taught by Sawan:

and an internal liquid holding member (15) which is made of porous substance having microscopic pores that hold the liquid therein in order to keep said film wet, and which is placed on upstream side of the filtration film (col. 11, lines 27 to 44); and a surface of said internal liquid holding member (15) is in contact with a surface of the filtration film (6).

Applicants disagree with this statement. The combination of Uetake and Sawan does not result in applicants' claimed invention so applicants' claimed invention is unobvious over such combination of two rejection references.

The Office Action stated that it would have been obvious to one having ordinary skill in the art at the time of the invention to have included the liquid holding member (pre-filter 15) of Sawan between the filter (7) and support seat (50) of Uetake in order to prevent clogging of the filter as explicitly taught by Sawan (col. 11, lines 27 to 49). Applicants traverse this statement for several reasons. Since the Examiner has not factually resolved the level of ordinary skill in the art, the Examiner does not know what would be obvious to one ordinarily skilled in the art. Section 103(a) requires facts not mere factually-unsupported speculation.

The Office Action stated that, since the liquid holding member (pre-filter 15) of Sawan is disclosed as having a pour size within the range disclosed by applicant, it would inherently perform in the same manner. Applicants traverse this statement as being mere factually-unsupported speculation. Applicants

request that the Examiner drop this statement unless he factually supports it by a reference or his own declaration.

The Office Action stated that, in reference to Claim 4, since the holding member (pre-filter 15) of Sawan has a larger pore size than the filter (6), the pressure necessary for the internal liquid to pass through the holding member from the upstream side to the downstream side is lower than filtration resistance of the filtration film. Again applicants request that the Examiner prove this statement by citation of a reference or his own declaration. The independent claim is unobvious so this dependent claim is unobvious.

The Office Action stated that in reference to Claim 5 see Uetake Fig. I and [0038]-[0041]. Independent Claim 1 is unobvious so dependent Claim 5 is also unobvious.

The Office Action stated that in reference to Claim 7 see Uetake Fig. I and [0046]. Independent Claim 1 is unobvious so dependent Claim 7 is also unobvious.

Withdrawal of this rejection is requested.

Claims 2 and 3 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Uetake in view of Sawan as applied to Claim 1 above, and further in view of Applicants Admitted Prior Art (AAPA). Applicants traverse this rejection. The combination of Uetake and Sawan does not result in applicants' claimed invention and the AAPA does not cure such defect in the rejection combination.

The Office Action stated: that, in reference to Claim 2, Uetake as modified by Sawan teaches a container with filter substantially according to Claim 1, but does not teach the particular filter according to the claim; and that the AAPA (specification page 11, line 15, to page 12, line 6) teaches that the claimer is a "Millipore Express Plus membrane filter", i.e., commercially available prior art filter. Independent Claim 1 is not obvious so dependent Claim 2 is not obvious.

The Office Action stated that it would have been obvious to one having ordinary skill in the art to have selected the AAPA Millipore Express Plus membrane filter for use in the device of Uetake since Uetake suggests that the use of any filter suited for preventing bacteria from entering the upstream side from the downstream side (see [0034]). Independent Claim 1 is unobvious so dependent Claim 2 is dependent. The Examiner does not know what would be obvious to one ordinarily skilled in the art.

The Office Action state that, further, the application of the AAPA filter to Uetake constitutes no more than combining prior art elements according to known methods to yield predictable results and the simple substitution of one known element for another to obtain predictable results supporting a conclusion of obviousness in accordance with the guidance of *KSR International Co. v Teleflex Inc.* (KSR), 550 U.S. \_\_, 82 USPQ2d 1385. Applicants traverse this statement as being meaningless until, as required by KSR, the level of ordinary skill in the art has been factually resolved. First things come first.

The Office Action stated that in reference to Claim 3 when AAPA prior art filter is used with Uetake as modified by Sawan, (with the same liquid) the device would inherently perform in the same manner. This statement is factually unproven. Independent Claim 1 is unobvious so dependent Claim 3 is also unobvious.

The Office Action stated that, further, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." (see MPEP 2144.05 II). The Examiner has not proven that only routine experimentation is involved. Sweeping statements are meaningless under Section 103(a).

Withdrawal of this rejection is requested.

Claims 1, 4, 5 and 7 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0130139 to Shiraishi et al. (Shiraishi) in view of U.S. Patent No. 6,030,632 to Sawan et al. (Sawan). Applicants traverse this rejection.

Applicants believe that the combination of Shiraishi and Sawan does not result in applicants claimed invention so applicants' claimed invention is not obvious over such rejection combination.

The Office Action stated that in reference to Claim 1 Shiraishi teaches:

A container with a filter (1) comprising:

a bottle (2) having a mouth portion (2a);

a plug body (3) placed on the mouth portion and providing a discharging pass (10) for discharging internal liquid kept in the bottle; a filter (7,50) provided in the discharging pass; said filter (7,50) has a filtration film (7) to filter out bacteria for preventing bacteria from percolating from downstream side to upstream side in the direction of discharging ([0034]).

Shiraishi does not teach or suggest applicants' claimed invention. Sawan does not cure the defects of Shiraishi in the search for applicants' claimed invention.

The Office Action stated that Shiraishi does not teach the following which is taught by Sawan:

and an internal liquid holding member (15) which is made of porous substance having microscopic pores that hold the liquid therein in order to keep said film wet, and which is placed on upstream side of the filtration film (col. 11, lines 27 to 44); and a surface of said internal liquid holding member (15) is in contact with a surface of the filtration film (6).

Applicants believe that the combination of Shiraishi and Sawan does not result in applicants' claimed invention.

The Office Action stated that it would have been obvious to one having ordinary skill in the art at the time of the invention to have included the liquid holding member (pre-filter 15) of Sawan between the filter (7) and support seat (50) of Shiraishi in order to prevent clogging of the filter as explicitly taught by

Sawan (col. 11, lines 27 to 49). The Examiner cannot make this statement as he has not factually resolved in the record the level of ordinary skill in the art.

The Office Action stated that, since the liquid holding member (pre-filter 15) of Sawan is disclosed as having a pour size within the range disclosed by applicant, it would inherently perform in the same manner. Applicants traverse this speculation. Section 103(a) requires facts.

The Office Action stated that, in reference to Claim 4, since the holding member (pre-filter 15) of Sawan has a larger pore size than the filter (6) the pressure necessary for the internal liquid to pass through the holding member from the upstream side to the downstream side is lower than filtration resistance of the filtration film. Applicants traverse this statement as being speculation.

The Office Action stated that, in reference to Claim 5, see Shiraishi Fig. 1 and [0056]-[0060]. Independent Claim 1 is unobvious so dependent Claim 5 is unobvious.

The Office Action stated that in reference to Claim 7 see Shiraishi Fig. 1 and [0067]. Independent Claim 1 is unobvious so dependent Claim 7 is unobvious.

Withdrawal of this rejection is requested.

Claim 6 has been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0130139 to Shiraishi et al. (Shiraishi) and No. 6,030,632 to Sawan et al. (Sawan) as applied to Claim 5 above and further in view of U.S. Patent 5,497,910 to Meadows et al. (Meadows).

Applicants traverse this rejection. Meadows does not cure the defects of the combination of Shiraishi and Sawan in the quest for applicants' claimed invention.

The Office Action stated that in reference to Claim 6 Shiraishi as modified by Sawan teaches:

A container with a filter (1) as set forth in claim 5 (see rejection of claim 1 above).

Independent Claim 1 is unobvious so dependent Claim 6 is also unobvious.

The Office Action stated that Shiraishi further teaches:

wherein a dispensing valve (8) has memory which expands said dispensing valve and generates negative pressure in the container so that a pressure difference between the negative pressure and an ambient pressure becomes higher than the filtration resistance thus liquid left downstream side of the filtration film is aspirated to upstream side of the filtration film (see [0043] and [0053]).

Independent Claim 1 is unobvious so dependent Claim 6 is also unobvious.

The Office Action stated that Shiraishi as modified by Sawan differs from the claim in that it is the resilient dispensing valve (8) and its associated connector sleeve (83) which cause the remaining liquid to be sucked into an upstream side of the filter rather than the memory of internal layer (22) which is disclosed to be made of a synthetic resin made of a resilient material (see [0057] and [0060]).

Applicants traverse this statement as regards applicants' claimed invention.

The Office Action stated that Meadows teaches:

In Figs. 1-3 of a dispenser similar to that of applicants' and Shiraishi to make an inner layer (inner bottle 30) from a resilient (compressible) material (LDPE) configured so as to create a "suck back" vacuum (see col. 4, lines 57 to 62; col. 5, lines 35 to 43).

The result is still not dependent Claim 6 (under amended independent Claim 1).

The Office Action stated that it would have been obvious to one having ordinary skill in the art at the time of the invention to have applied the teaching of using the characteristics of the compressible inner bottle to suck back liquid into the inner layer of Meadows in the dispenser of Shiraishi as modified by Sawan because doing so would allow the suck back function to be performed without the use of a resilient valve. Applicants traverse this statement. The Examiner does not know what would have been obvious to one ordinarily skilled in the art because the Examiner has not factually resolved in the record the level of ordinary skill in the art. The Examiner has not carried his burden of proof.

The Office Action stated that further the application of the teaching of Meadows to Shiraishi as modified by Sawan constitutes no more than combining prior art elements according to known methods to yield predictable results and the use of a known technique to improve similar device in the same way supporting a conclusion of obviousness in accordance with the guidelines of *KSR International Co. v. Teleflex Inc.* (KSR), 550 U.S. \_\_, 82 USPQ2d 1385. Applicants traverse

this statement as it not supported by facts, proof, etc. Also it does not follow the requirements of the KSR decision so it is of no weight under Section 103(a).

Withdrawal of this rejection is requested.

Reconsideration, reexamination and allowance of the claims are requested.

Respectfully submitted,

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Date

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pass through said holding member from upstream side to downstream side lower than filtration resistance of the filtration film. According to this, dischargeability of the internal liquid is not blocked, since the whole filtration resistance of both the filtration film and the holding member is equal to the filtration resistance of only the filtration film, even after placing the internal liquid holding member. It is possible to set the filtration resistance between 10hPa and 50hPa or between 10hPa and 20hPa as well, and it is preferable to set this resistance as low as possible.

The bottle may have an external layer bottle which is deformable by 10 squeezing and an internal layer bag which is peelable from the external layer bottle, and said liquid may be kept in the internal layer bag. It is possible to increase a pressure of air between the external layer bottle and the internal layer bag, and it is possible to place in a manner wherein the internal layer bag is pressed by the pressurized air so that the liquid in the internal layer bag passes 15 through said internal liquid holding member and said filtration film. The internal layer bag may be formed to deflate easily accompanying the decrease of the internal liquid. If the filtration film is formed from the thin hydrophilic membrane, in the condition wherein it is wet, it is possible to shut out air by the filtration film. Thus it is possible to prevent ambient air from flowing into the 20 internal layer bag. Therefore it is possible to form an aseptic eyedropper which does not require preservation agents.

Preferably the internal layer bag has memory which expands said internal layer bag and generates negative pressure in the internal layer so that a pressure difference between the negative pressure and the ambient pressure becomes 25 higher than the filtration resistance thus liquid left downstream side of the filtration film is aspirated to upstream side of the filtration film. Hereby it is possible to prevent the liquid left downstream side of the filtration film from

staying there and to prevent bacteria from growing in the left liquid.

Also, in the present invention, it is preferable that the body of the inner layer is made from synthetic resin, the average thickness of the body is over 0.1mm, more preferably, over 0.35mm, and the average thickness of the body is 5 less than 0.5mm, more preferably, less than 0.4mm. By that, the inner layer can be formed to have a desired elastic-memory.

Additionally, in the present invention, it is preferable to employ the composition in which the outer layer has an entry opening to bring the outside air in the room between the outer layer and the inner layer. By that, when pushing 10 of the bottle is released, the ambient air flows in through the entry opening and the pressure between the outer layer and the inner layer becomes the ambient pressure, so that the difference of the pressure between the upper stream of the filter and the lower stream of the filter caused by the elastic-memory of the inner layer can be in the desired range without fail. It is possible to provide the 15 distribution valve for the entry opening, but it is also possible to form the entry opening with an opening which is closed when the body of the bottle is pushed.

According to the present invention, especially in eyedroppers and the like, it is possible to prevent air bubbles from being generated around the discharging pass so that internal liquid is dropped smoothly and precisely.

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#### BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is scale-up longitudinal sectional view of the relevant part of the eyedropper with a laminated film-peeling bottle of an embodiment of the present invention;

25 Fig. 2 is whole longitudinal sectional view of said eyedropper;

Fig. 3 is whole picture of the laminated film-peeling bottle of said eyedropper, which (a) is a plane view and (b) is an elevated view;